



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HU *et al.*

Appl. No.: 09/219,442

Filed: December 23, 1998

For: **Vascular Endothelial Growth  
Factor 2 and Methods of Use**

Confirmation No.: 4797

Art Unit: 1647

Examiner: Landsman, Robert S.

Atty. Docket: 1488.100000I/HCC/LMB

**Twelfth Supplemental Information Disclosure Statement  
Under 37 C.F.R. § 1.97(b)**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Forms PTO/SB/08A and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Twelfth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Eleventh Supplemental Information Disclosure Statement filed on February 3, 2006 in connection with the above-captioned application.

Copies of documents **FP13-FP23** and **NPL49-NPL83** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents, documents **US14-US20**, cited on the attached Form PTO/SB/08A are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **FP14** and **FP15** cited on Form PTO/SB/08A:

Document **FP14**, JP 64-38100 A, is in the Japanese language. An English language abstract of document FP14 is attached as document **NPL55**.

Document **FP15**, JP 2-117698 A, is in the Japanese language. An English language abstract of document FP15 is attached as document **NPL56**.

Applicants would also like to bring to the attention of the Examiner that, for the following documents, the months of publication could not be determined to the best of the Applicants' ability: **NPL72**, Spranger, J. and Pfeiffer, A.F.H., "New concepts in pathogenesis and treatment of diabetic retinopathy," *Exp. Clin. Endocrinol. Diabetes* 109(Suppl. 2):S438-S450, J.A. Barth Verlag (2001); and **NPL73**, Stacker, S.A. and Achen, M.G., "The Vascular Endothelial Growth Factor Family: Signalling for Vascular Development," *Growth Factors* 17:1-11, Taylor & Francis (1999)

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson  
Agent for Applicants  
Registration No. 47,473

Date: March 14, 2006

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Substitute for form 1449/PT

**TWELFTH SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Sheet	1	of	2
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**Complete if Known**

Application Number	09/219,442
Filing Date	December 23, 1998
First Named Inventor	Jing-Shan HU
Art Unit	1647
Examiner Name	Landsman, Robert S.
Attorney Docket Number	1488.100000I/HCC/LMB

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	FP13	EP 0 186 084 A2	07/02/1986	Merck & Co. Inc.		
	FP14	JP 64-38100 A	02/08/1989	Toray Ind. Inc.		
	FP15	JP 2-117698 A	05/02/1990	Ajinomoto KK and Toray Ind. Inc.		
	FP16	EP 0 399 816 A1	11/28/1990	Merck & Co. Inc.		
	FP17	WO 94/11506 A1	05/26/1994	Arch Development Corporation		
	FP18	WO 00/45835 A1	08/10/2000	Human Genome Sciences, Inc. and Rosen <i>et al.</i>		
	FP19	WO 02/11769 A1	02/14/2002	Human Genome Sciences, Inc. and Coleman		
	FP20	WO 02/083704 A1	10/24/2002	Human Genome Sciences, Inc. and Rosen <i>et al.</i>		

Examiner Signature		Date Considered	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	FP21	WO 02/083849 A2	10/24/2002	Human Genome Sciences, Inc. and Rosen <i>et al.</i>		
	FP22	WO 02/083850 A2	10/24/2002	Human Genome Sciences, Inc. and Rosen <i>et al.</i>		
	FP23	WO 03/097660 A1	11/27/2003	Human Genome Sciences, Inc. and Rosen <i>et al.</i>		

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL49	Borg, J.-P., <i>et al.</i> , "Biochemical characterization of two isoforms of FLT4, a VEGF receptor-related tyrosine kinase," <i>Oncogene</i> 10:973-984, Stockton Press (March 1995)	
	NPL50	Capogrossi, M.C., "Gene Therapy of Coronary Artery Disease," Project No. Z01 AG00811-01, Abstract (January 1994)	
	NPL51	Capogrossi, M.C., "Gene Therapy of Coronary Artery Disease," Project No. Z01 AG00811-02, Abstract (January 1995)	
	NPL52	Choi, I.H., <i>et al.</i> , "Angiogenesis and Mineralization During Distraction Osteogenesis," <i>J. Korean Med. Sci.</i> 17:435-447, The Korean Academy of Medical Sciences (August 2002)	
	NPL53	Copy of Declaration of Dr. Kari Alitalo, In re of: U.S. Application No. 08/585,895, Alitalo <i>et al.</i> , filed January 12, 1996, submitted November 26, 1997	
	NPL54	Dias, S., <i>et al.</i> , "Vascular endothelial growth factor (VEGF)-C signaling through FLT-4 (VEGFR-3) mediates leukemic cell proliferation, survival, and resistance to chemotherapy," <i>Blood</i> 99:2179-2184, The American Society of Hematology (March 2002)	
	NPL55	English language abstract of JP 64-38100 A, cited as document FP14 on Form PTO/SB/08A, Derwent Accession No. 1989-088700/198912	
	NPL56	English language abstract of JP 2-117698 A, cited as document FP15 on Form PTO/SB/08A, Derwent Accession No. 1990-181364/199024	
	NPL57	Fan, T.-P.D., <i>et al.</i> , "Controlling the vasculature: angiogenesis, anti-angiogenesis and vascular targeting of gene therapy," <i>Trends Pharmacol. Sci.</i> 16:57-66, Elsevier Science Ltd. (February 1995)	
	NPL58	Isner, J.M., <i>et al.</i> , "Arterial Gene Therapy for Therapeutic Angiogenesis in Patients With Peripheral Artery Disease," <i>Circulation</i> 91:2687-2692, American Heart Association, Inc. (June 1995)	

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	NPL59	Isner, J.M. and Feldman, L.J., "Gene therapy for arterial disease," <i>Lancet</i> 344:1653-1654, The Lancet Ltd. (December 1994)	
	NPL60	Isner, J.M., <i>et al.</i> , "Physiologic Assessment of Angiogenesis by Arterial Gene Therapy with Vascular Endothelial Growth Factor," <i>J. Cell. Biochem. (Suppl. 21A)</i> :378, Abstract C6-215, Wiley-Liss (March-April 1995)	
	NPL61	Isner, J.M., "Therapeutic Angiogenesis in Vascular Medicine," Project No. R01 HL53354-01, Abstract (March 1995)	
	NPL62	Kubo, H., <i>et al.</i> , "Blockade of vascular endothelial growth factor receptor-3 signaling inhibits fibroblasts growth factor-2-induced lymphangiogenesis in mouse cornea," <i>Proc. Natl. Acad. Sci.</i> 99:8868-8873, The National Academy of Sciences (June 2002)	
	NPL63	Kuzuya, M. and Kinsella, J.L., "Induction of Endothelial Cell Differentiation <i>in Vitro</i> by Fibroblast-Derived Soluble Factors," <i>Exp. Cell Res.</i> 215:310-318, Academic Press, Inc. (December 1994)	
	NPL64	Maher, P.A., "Stimulation of Endothelial Cell Proliferation by Vanadate Is Specific for Microvascular Endothelial Cells," <i>J. Cell. Physiol.</i> 151:549-554, Wiley-Liss, Inc. (1992)	
	NPL65	Mesri, E.A., <i>et al.</i> , "Expression of Vascular Endothelial Growth Factor From a Defective Herpes Simplex Virus Type 1 Amplicon Vector Induces Angiogenesis in Mice," <i>Circulation Res.</i> 76:161-167, American Heart Association, Inc. (February 1995)	
	NPL66	Mühlhauser, J., <i>et al.</i> , "In Vivo Gene Transfer into Porcine Cardiac Cells with a Replication-Deficient Recombinant Adenovirus Vector," <i>Circulation</i> 88:I-475, Abstract No. 2558, American Heart Association (October 1993)	
	NPL67	Mühlhauser, J., <i>et al.</i> , "VEGF <sub>165</sub> Expressed by a Replication-Deficient Recombinant Adenovirus Vector Induces Angiogenesis In Vivo," <i>Circulation Res.</i> 77:1077-1086, American Heart Association, Inc (December 1995)	
	NPL68	Oikawa, T., <i>et al.</i> , "Three Isoforms of Platelet-Derived Growth Factors All Have the Capability to Induce Angiogenesis <i>In Vivo</i> ," <i>Biol. Pharm. Bull.</i> 17:1686-1688, (December 1994)	

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Sheet	3	of	4	Attorney Docket Number	1488.100000I/HCC/LMB

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL69	Pajusola, K., <i>et al.</i> , "Signalling properties of FLT4, a proteolytically processed receptor tyrosine kinase related to two VEGF receptors," <i>Oncogene</i> 9:3545-3555, Stockton Press Ltd. (December 1994)	
	NPL70	Pepper, M.S., <i>et al.</i> , "In Vitro Angiogenic and Proteolytic Properties of Bovine Lymphatic Endothelial Cells," <i>Exp. Cell Res.</i> 210:298-305, Academic Press, Inc. (January 1994)	
	NPL71	Plate, K.H., "From angiogenesis to lymphangiogenesis," <i>Nat. Med.</i> 7:151-152, Nature America, Inc. (February 2001)	
	NPL72	Spranger, J. and Pfeiffer, A.F.H., "New concepts in pathogenesis and treatment of diabetic retinopathy," <i>Exp. Clin. Endocrinol. Diabetes</i> 109(Suppl. 2):S438-S450, J.A. Barth Verlag (2001)	
	NPL73	Stacker, S.A. and Achen, M.G., "The Vascular Endothelial Growth Factor Family: Signalling for Vascular Development," <i>Growth Factors</i> 17:1-11, Taylor & Francis (1999)	
	NPL74	Symes, J.F. and Sniderman, A.D., "Angiogenesis: potential therapy for ischaemic disease," <i>Curr. Opin. Lipidol.</i> 5:305-312, Current Science Ltd. (August 1994)	
	NPL75	Takeshita, S., <i>et al.</i> , "In Vivo Evidence of Enhanced Angiogenesis Following Direct Arterial Gene Transfer of the Plasmid Encoding Vascular Endothelial Growth Factor," <i>Circulation</i> 88:I-476, Abstract No. 2565, American Heart Association (October 1993)	
	NPL76	Takeshita, S., <i>et al.</i> , "Therapeutic Angiogenesis. A Single Intraarterial Bolus of Vascular Endothelial Growth Factor Augments Revascularization in a Rabbit Ischemic Hind Limb Model," <i>J. Clin. Invest.</i> 93:662-670, The American Society for Clinical Investigation, Inc. (February 1994)	
	NPL77	Walsh, D.A. and Pearson, C.I., "Angiogenesis in the pathogenesis of inflammatory joint and lung diseases," <i>Arthritis Res.</i> 3:147-153, BioMed Central Ltd. (February 2001)	
	NPL78	Williams, R.S., "Southwestern Internal Medicine Conference: Prospects for Gene Therapy of Ischemic Heart Disease," <i>Am. J. Med. Sci.</i> 306:129-136, Lippincott Williams & Wilkins (August 1993)	

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	NPL79	Witzenbichler, B., <i>et al.</i> , "Vascular Endothelial Growth Factor-C (VEGF-C/VEGF-2) Promotes Angiogenesis in the Setting of Tissue Ischemia," <i>Am. J. Pathol.</i> 153:381-394, American Society for Investigative Pathology, Inc. (August 1998)	
	NPL80	Yeung, P.K.F., "VEGF-2," <i>Curr. Opin. Invest. Drugs</i> 2:796-800, PharmaPress Ltd. (June 2001)	
	NPL81	Anderson, W.F., "Human gene therapy," <i>Nature</i> 392:25-30, Macmillan Magazines Ltd. (April 1998)	
	NPL82	Maynard, J. and Georgiou, G., "Antibody Engineering," <i>Annu. Rev. Biomed. Eng.</i> 2:339-376, Annual Reviews (August 2000)	
	NPL83	Morea, V., <i>et al.</i> , "Antibody Modeling: Implications for Engineering and Design," <i>Methods</i> 20:267-279, Academic Press (March 2000)	

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